REMARKS

Claims 1-44 were pending in the present application. Claims 1, 26, 31, 32, 34, 36 and 40 have been amended and claims 7-10, 30 and 33 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Claim 1 has been amended to include the subject matter of canceled claim 30. Claims 26 and 40 have been made independent claims. Claims 31 and 32 were amended to reflect the cancellation of claim 30, upon which these claims originally depended. Claim 34 was amended to recite an adhesive substance applied over substantially the entire bottom side of the flexible material. Claim 36 was amended to correct a minor error.

New claims 45-55 were added. Support for the new claims may be found in the original claims and at paragraphs [0060] and [0076] of the application as filed. No new matter was added. Claims 1-6, 11-29, 31-32 and 34-55 are now pending.

Reexamination of the application and reconsideration of the rejections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

Claims 1-23, 25, 34-39 and 41-44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark et al., U.S. Patent No. 5,259,835 (hereinafter "Clark"), in view of Ballance et al., U.S. Patent No. 6,439,789 (hereinafter "Ballance"). Applicants respectfully traverse this rejection.

Clark describes a wound closure device which employs a porous bonding member which receives a flowable adhesive which may be a cyanoacrylate. According to Clark, a flowable, fast setting, high strength adhesive is introduced into the bonding pad to bond the pad to the skin at opposite wound margins. *Column 1, lines 44-48.*

Ballance is directed to polymerizable 1,1-disubstituted ethylene monomer formulation applicators, applicator tips and applicator kits. The monomer may be surrounded by a container that may be engaged with an applicator tip. The applicator tip may have an internal cavity defined in an applicator tip body and a porous material member may be connected to the applicator tip body to be in fluid communication with the internal cavity. Bioactive agents, viscosity modifiers, initiators, inhibitors and/or stabilizers may be added to the applicator, preferably in or on the porous material member. *Abstract.*

Claim 1, as amended, is directed to a tissue bonding article comprising a flexible material, an adhesive substance applied over substantially the entire bottom side of the

flexible material and a polymerizable adhesive composition permeated throughout at least a portion of the flexible material.

Claim 34, as amended, is directed to a method of bonding tissue, comprising placing a flexible substrate over a section of tissue, wherein the flexible substrate comprises a flexible material and an adhesive substance applied over substantially the entire bottom side of the flexible material; applying a polymerizable adhesive composition over and substantially covering at least a portion of the flexible substrate; and allowing the polymerizable adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to the tissue.

Clark is directed to wound closure means wherein a skin contact adhesive may be used for temporarily apposing the edges of a wound. *Column 1, lines 50-51.* The application of the skin contact adhesive is shown in the figures of Clark at, for example, element 40 in FIG. 2. As shown in FIG. 2 and described in the specification:

> The wound closure device 30 includes means for holding the wound in apposed position and holding the bonding pad 36 in place during the time the adhesive bond between the bonding pad and the skin is being formed. In this regard, the intermediate portions 32b include a contact adhesive 40 on the underside thereof for at least temporarily holding the carrier member 32 onto the skin. Such contact adhesive may also be applied in a discontinuous fashion (indicated as portions 40a) to the skin contact side of the bonding pad 36 as shown in FIG. 2. The discontinuous application of contact adhesive to the bonding pad 36 is desirable so that portions of the bonding pad wetted with the flowable adhesive are in contact with and can form a bond with the skin.

Column 4, lines 27-41. Thus, Clark shows the use of skin contact adhesive on the edges of the bonding pad or applied in a discontinuous fashion. Clark does not disclose or suggest the use of an adhesive substance applied over substantially the entire bottom side of flexible material as claimed. Moreover, Clark *teaches away* from using an adhesive substance applied over substantially the entire bottom side of flexible material since Clark specifically teaches that the discontinuous application of contact adhesive is desirable so that portions of the bonding pad wetted with the flowable adhesive are in contact with and can form a bond with the skin.

The combination of Ballance with Clark would not have made the modification of Clark obvious to those of ordinary skill in the art since Ballance is directed to an applicator

and does not disclose a bonding pad or include teachings regarding an adhesive substance thereon.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must some suggestion or motivation, either in the references themselves or in the knowledge in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the cited art reference or references when combined must teach or suggest all the claim limitations. *See MPEP § 2143.* These criteria have not been met here since, as noted, Clark teaches away from a tissue bonding article and method of bonding tissue as claimed. Review of Clark would have led one of skill in the art to believe that use of an adhesive substance applied over substantially the entire bottom side of a flexible material would prevent the flowable adhesive taught in Clark from properly bonding with the skin. Thus, there would have been no reasonable expectation of success. Moreover, neither Clark nor Ballance teach or suggest all the claim limitations since the adhesive substance applied as claimed is lacking. In view thereof, a *prima facie* case has not been made and Applicants respectfully request that this rejection be withdrawn.

Clark and Ballance also would not have made the subject matter defined in the new claims 46-54 obvious. New claim 46 is directed to a tissue bonding article comprising a flexible material; an adhesive substance applied over at least a portion of a bottom side of said flexible material; and a polymerizable adhesive composition applied over an entire surface of the flexible material and permeated throughout at least a portion of the flexible material. New claim 54 is directed to a method of bonding tissue, comprising placing a flexible substrate over a section of tissue, wherein the flexible substrate comprises a flexible material and an adhesive substance applied over at least a portion of a bottom side of the flexible material; applying a polymerizable adhesive composition over and substantially covering an entire surface of the flexible substrate; and allowing the polymerizable adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to the tissue.

The Clark patent discloses specific ports or locations for application of the flowable adhesive. *Column 4, lines 3-5, column 4, line 67 – column 5, line 2, and FIGS.* As explained in the present specification, however, the polymerizable adhesive composition is preferably applied over an entire surface of the flexible substrate.

> That is, while the flexible substrate may provide some wicking, flowing, or capillary movement of the polymerizable adhesive composition within the bulk material of the flexible substrate, such wicking or capillary movement is minimal, and is not intended to provide complete coverage of the polymerizable adhesive composition over the flexible substrate. Thus, for example, it will generally not be possible to apply one or two drops of the polymerizable adhesive composition to the flexible substrate, and expect the polymerizable adhesive composition to completely cover the flexible substrate (unless, of course, the flexible substrate is such a small size that the drops substantially cover the surface). Rather, in embodiments of the present invention, the polymerizable adhesive composition is applied by dabbing, brushing, rolling, painting, swabbing or the like, the polymerizable adhesive composition onto the flexible substrate.

Specification, paragraph [0076]. Thus, new claims 46-54 are believed to be patentable over any presently cited art.

Claims 24, 26, 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark and Ballance in view of Porzilli, U.S. Patent No. 5,336,209. Applicants respectfully traverse this rejection.

Claim 24, 28 and 29 are dependent on amended claim 1. Clark and Ballance are discussed above. Porzilli is directed to a protective wound bandage which allows for the ability to regulate and monitor oxygen flow to the injury site. Porzilli does not remedy the deficiencies of the combination of Clark and Ballance as described above since Porzilli does not disclose or suggest an adhesive substance applied over substantially the entire bottom side of a flexible material as claimed. In view thereof, Applicants respectfully request that the rejection as to these claims be withdrawn.

Claim 26 has been rewritten as an independent claim directed to a tissue bonding article, comprising a flexible material; an adhesive substance applied over at least a portion of a bottom side of the flexible material; and a polymerizable adhesive composition permeated throughout at least a portion of the flexible material, wherein the flexible material and the polymerizable adhesive composition are together biodegradable.

Clark does not disclose a flexible material and a polymerizable adhesive composition which are together biodegradable. Ballance also does not disclose such a combination. Porzilli describes a dressing which can be manufactured from biodegradable materials if so desired, states that the skin release adhesive covering strip 24 would be manufactured in a biodegradable material in the preferred embodiment, and indicates that the tear tab cover 14

is, in a preferred embodiment, manufactured from a translucent, opaque or clear biodegradable material. *Column 2, lines 13-14, 35-36 and 66-68.* However, Porzilli does not disclose or suggest a material wherein there is a flexible material and a polymerizable adhesive composition which are together biodegradable. Rather, Porzilli does not teach or suggest a biodegradable adhesive at all.

According to the Office Action, it would have been obvious to a person having ordinary skill in the art to combine Porzilli's biodegradable material with one of the known biodegradable adhesives so that the article will not need to be removed and is environmentally friendly. *Office Action mailed August 21, 2006, page* 8. This analysis requires hindsight that could only be drawn from review of the invention as defined in the rejected claim. Simply identifying all of the elements in a claim in the prior art does not render a claim obvious. *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.,* 411 F.3d 1332, 1338 (Fed. Cir. 2005).

Porzilli does not disclose a biodegradable adhesive, although other parts of the dressing may be biodegradable. Some cyanoacrylates may be biodegradable, but this characteristic is not discussed in Clark. No reason is provided in any of the cited art to use the combination of materials forming the composite structure (i.e., the flexible material and the polymerizable adhesive composition) together to be biodegradable. In view thereof, none of the cited patents discloses or suggests the tissue bonding article defined in claim 26 and Applicants respectfully request that this rejection be withdrawn.

Claim 27 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark and Ballance. Applicants respectfully traverse this rejection.

Claim 27 is dependent on claim 1. For the reasons discussed above with regard to claim 1, a *prima facie* case of obviousness has not been made since the combination of Clark and Ballance would not have led one of ordinary skill in the art to the tissue bonding article defined in claim 1. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claim 40 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark and Balance in view of VanDruff, U.S. Patent Application Publication No. 2002/0193721. Applicants respectfully traverse this rejection.

Claim 40 is directed to a method of bonding tissue. The method comprises placing a flexible substrate over a section of tissue wherein the section of tissue includes a wound to be

closed and wherein the flexible substrate comprises a flexible material and an adhesive substance applied over at least a portion of a bottom side of the flexible material. The method further comprises applying a polymerizable adhesive composition over and substantially covering at least a portion of the flexible substrate and allowing the polymerizable adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to the tissue. The placing of the flexible substrate comprises fixing a first lengthwise end of the flexible substrate to the section of tissue on a first lengthwise end of the wound; approximating edges of the wound; and fixing a second lengthwise end of the flexible substrate to the section of tissue on a second lengthwise end of the wound opposite the first lengthwise end of the wound.

As noted in the Office Action, Clark and Ballance do not disclose the recitations of claim 40. VanDruff is directed to a wound closure grid tape apparatus and method. VanDruff is meant to provide external stitches in about the same spacing as traditional stitches that are held in place by cross-members and adhesion to the skin. The "stitch" can be thought of as being planar to the skin and deriving its strength to hold the wound closed from adhesion by cross-members at right angles to the wound, and also from the circuits created by the cross-members of the grid structure rather than by looping into and through the skin surface. *Paragraph [0032].* Clark describes wound apposition as taught therein as accomplished initially by means of a member extending across the wound and longer term, more permanent apposition is achieved by application of a flowable adhesive to a porous bonding member. *Column 10, lines 19-23.* Since VanDruff was solving the problem with stitches by providing a grid which approximates the function of stitches and Clark uses a completely different system of a flowable adhesive system, placing a member across the wound, there would have been no motivation for modifying the wound closure system of Clark to apply the system as taught for the grid tape of VanDruff. In view thereof, Applicants respectfully request that the rejection be withdrawn.

For the foregoing reasons, claims 1-6, 11-29, 31-32 and 34-55 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-3218.

Respectfully submitted,

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